

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA

LARADA SCIENCES, INC.)	
)	
Plaintiff,)	
)	
v.)	CIVIL ACTION FILE NO.
)	3:18-cv-320
PEDIATRIC HAIR SOLUTIONS)	
CORPORATION, AND FLOSONIX)	
VENTURES, LLC)	
)	
Defendants.)	
_____)	

COMPLAINT

Comes now Plaintiff Larada Sciences, Inc. and files this complaint against Defendants Pediatric Hair Solutions Corporation (“PHS”) and FloSonix Ventures, LLC (“FloSonix”), and alleges as follows:

PARTIES

1. Plaintiff Larada Sciences, Inc. (“Larada”) is a corporation organized under the laws of the State of Delaware, with its principal place of business at 154 East Myrtle Avenue, Suite 304, Murray, Utah 84107.

2. Defendant PHS is a North Carolina company with a principal place of business at 6923 Shannon Willow Road., Suite 100, Charlotte, North Carolina 28226.

3. Defendant FloSonix is a Wyoming company with a principal place of business at 6923 Shannon Willow Road, Suite 100, Charlotte, North Carolina 28226.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 et seq.

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has jurisdiction over PHS because PHS has its principal place of business in this District.

7. This Court has jurisdiction over FloSonix because FloSonix has its principal place of business in this District.

8. Venue as to PHS is proper in this District pursuant to 28 U.S.C. §1400(b) because PHS resides in this District, has a regular and established place of business in this District, and has committed acts of infringement in this District. Those acts of infringement include practicing and inducing the practicing of methods that infringe the Patents-in-Suit, and by making, using, offering to sell, selling, and/or having sold a device that infringes the Patents-in-Suit.

9. Venue as to FloSonix is proper in this District pursuant to 28 U.S.C. §1400(b) because FloSonix has a regular and established place of business in this District and has committed acts of infringement in this District. Those acts of infringement include practicing and inducing the practicing of methods that infringe the Patents-in-Suit, and by making, using, offering to sell, selling, and/or having sold a device that infringes the Patents-in-Suit.

10. Joinder of Defendants in this suit is proper under 35 U.S.C. § 299 because Defendants' acts of infringement are based on the making, using, importing into the United States, offering for sale, or selling of the same accused product or process – namely the FloSonix device – and that questions of fact common to all Defendants will arise in this action, including whether making, using, offering to sell, selling, and/or having sold the FloSonix device constitutes direct or indirect infringement of the Patents-in-Suit.

THE PATENTS-IN-SUIT

11. United States Patent Number 7,789,902 (“the ‘902 Patent”) is entitled “Ectoparasite Eradication Method and Device.” The ‘902 Patent was filed on November 23, 2005, and was duly and legally issued by the United States Patent and Trademark Office on September 7, 2010. The ‘902 Patent is assigned to the University of Utah Research Foundation, and Larada has an exclusive license to

the '902 Patent, including the right to enforce for past, present, and future infringement. A true and correct copy of the '902 Patent is attached hereto as Exhibit A.

12. United States Patent Number 8,162,999 ("the '999 Patent") is entitled "Ectoparasite Eradication Method and Device." The '999 Patent was filed on September 3, 2010, and was duly and legally issued by the United States Patent and Trademark Office on April 24, 2012. The '999 Patent is assigned to the University of Utah Research Foundation, and Larada has an exclusive license to the '999 Patent, including the right to enforce for past, present, and future infringement. A true and correct copy of the '999 Patent is attached hereto as Exhibit B.

13. United States Patent Number 8,475,510 ("the '510 Patent") is entitled "Airflow applicators and related treatment methods." The '510 Patent was filed on September 23, 2009, and was duly and legally issued by the United States Patent and Trademark Office on July 2, 2013. Larada is the owner of all right and title to the '510 Patent. A true and correct copy of the '510 Patent is attached hereto as Exhibit C.

14. United States Design Patent Number D626,287 ("the D287 Patent") is entitled "Airflow attachment." The D287 Patent was filed on September 23, 2009

and was duly and legally issued by the United States Patent and Trademark Office on October 26, 2010. Larada is the owner of all right and title to the D287 Patent. A true and correct copy of the D287 Patent is attached hereto as Exhibit D.

15. Larada has, to the extent required, complied with the marking provisions of 35 U.S.C. § 287 for all time periods relevant to PHS's infringement of the '902 Patent, the '999 Patent, the '510 Patent, and the D287 Patent (collectively, "the Patents-in-Suit").

THE AIRALLÉ LICE ERADICATION DEVICE

16. The Patents-in-Suit relate to methods and devices for eliminating ectoparasites, such as head lice.

17. A head lice infestation can be difficult to treat. Traditionally, removal of head lice (and their eggs) involved a time-intensive and tedious manual process using a louse comb to remove lice and their eggs from an individual's hair. Chemical treatments exist, but can be undesirable because lice have developed a resistance to many such treatments, and because these treatments involve pesticides that many people do not want to apply to their bodies.

18. Researchers at the University of Utah, including Dale H. Clayton, Ph.D., the first inventor named on the '902 and '999 Patents, developed methods involving heating air to a certain temperature and applying the heated air to a

human head to effectively eliminate lice infestations without the use of chemicals. The researchers also developed a device called the “LouseBuster” to carry out these methods.

19. Larada was formed in 2006 to bring the LouseBuster to market. Larada obtained an exclusive license to the ‘902 and ‘999 Patents, including the right to enforce the ‘902 and ‘999 Patents.

20. Through further research and development, Larada continued to refine the LouseBuster and the techniques for using the device. This development led to the ‘510 Patent and the D287 Patent.

21. Ultimately, the LouseBuster was renamed “AirAllé.”

22. Larada’s business model is to license to individuals and businesses the rights to use AirAllé devices in performing lice treatments in an exclusive territory, either under a license agreement or a franchise agreement. The license and franchise agreements include training in, among other things, how to use the AirAllé to perform the methods claimed in the ‘902 Patent, the ‘999 Patent, and the ‘510 Patent. Prior to signing license and franchise agreements, Larada’s business model was to lease the AirAllé device to individuals and businesses wishing to perform lice treatments using the device.

23. More than 250 license and franchise agreements currently allow AirAllé devices to perform head lice treatments in the United States, with 200 U.S. clinics actively treating head lice using the AirAllé device in exclusive territories.

24. The '902 Patent, the '999 Patent, and the '510 Patent reflect a novel solution to the problem of treating lice infestations. It is not the case that simply applying heated air to a head lice infestation can effectively treat lice. Rather, until Dr. Clayton and his team at the University of Utah developed the LouseBuster and the methods for treating lice claimed in the '902 Patent and the '999 Patent, and then Larada further developed those methods as claimed in the '510 Patent, it was generally understood that even though heated air had been shown to kill lice and their eggs in vitro, these treatments were not effective in vivo. Only through the novel and inventive methods that are described and claimed in the '902 and '999 Patents, and further improvements in the '510 Patent did it become possible to use heated air to treat a lice infestation.

25. The claims of the '902 Patent, the '999 Patent, and the '510 Patent recite a series of tangible steps directed to applying heated air in such a way as to deliver the heated air at the proper angle and location so as to eradicate the lice infestation. The claims of the '902 Patent and the '999 Patent require a certain temperature range, and in some cases, a certain airflow, while the '510 Patent

requires use of an applicator with ports of a particular configuration. These inventive methods are limited to applications of heated air involving specific parameters (including temperature, volumetric airflow, and time of application) that the inventors have determined as being effective to achieve the in vitro eradication of lice infestations while being suitable for application to the scalp. The specifications of the Patents-in-Suit include specific examples to illustrate the accurate measurement of volumetric airflow rates according to the claimed treatment methods. Certain of the inventive methods also involve the use of a comb device to further increase lice mortality rates regardless of hair length. As such, the claimed treatment elements of the '902 Patent, the '999 Patent, and the '510 Patent are sufficiently limited to ensure that the patents do not monopolize a law of nature. Furthermore, the claims do not describe well-understood, routine, or conventional activities. Rather, they claim techniques for the treatment of lice infestations with heated air which—before the Patents-in-Suit and the LouseBuster/AirAllé—was believed to be an ineffective approach to treating lice infestations.

PHS'S USE OF AND PRAISE FOR LARADA'S PATENTED TECHNOLOGY

26. At one time, PHS was one of the many businesses that Larada allowed to use the AirAllé device in exclusive territories. Initially Larada did this through lease agreements and later through license agreements.

27. Starting on November 16, 2010, PHS began leasing the AirAllé device under a lease agreement. Beginning on August 31, 2015, PHS and Larada converted that lease agreement to multiple license agreements, each for a specific territory in which PHS had exclusive rights to use the AirAllé device. Along with the lease and licensing rights to use the AirAllé device, PHS paid for the right to receive Larada's knowhow, the use of Larada's trademarks to develop a lice treatment business, and nationwide support from Larada as PHS built its business from a single clinic to nine clinics when the license agreements were terminated on March 10, 2017.

28. As early as March 29, 2012, PHS publicly praised the AirAllé device, including a demonstration on local news that PHS reproduced on YouTube. PHS displayed its logo over the video it showed on its website.

29. The YouTube video is available at
<https://www.youtube.com/watch?v=5LEXrJnUb9w>

30. In the video, PHS's owner Sheila Fassler describes the AirAllé (then still known as the LouseBuster), the process for using it, and the incredible results the AirAllé was able to achieve. Ms. Fassler states "Within the last year the LouseBuster device has been developed. I apply controlled warm air to the child's head in a sequential manner for about 30 minutes and it dehydrates everything. Kills everything in the head. When the 30 minute treatment's done, your problem is done."

31. Ms. Fassler goes on to describe how, before the AirAllé, there were only two methods of treating lice: the use of harsh chemicals and manually removing lice, nits, and eggs from the hair. Ms. Fassler describes the drawbacks with those approaches and how the AirAllé solved those problems.

32. Ms. Fassler states: "The toxins and pesticides that they sell at the drug store and the big superstores, their efficiency has gotten much less because the lice have developed a resistance. The other option would be to have someone come into your home or you as a parent pick through the hair for hours over a three week period of time until you pick every miniscule egg out of your child's head."

33. Ms. Fassler then goes on to praise the AirAllé. She says: "The LouseBuster is 99.2 percent effective. No other treatment can claim that. They leave the .8 percent for human error."

34. The segment goes on to report that “This non-toxic treatment is 100 percent effective with no side effects.”

35. Ms. Fassler describes treatment with the AirAllé as “a permanent solution.”

DEFENDANTS’ WILLFUL INFRINGEMENT OF THE PATENTS-IN-SUIT

36. Through correspondence with Larada, including the lease agreement and license agreements through which PHS purchased the ability to use the AirAllé, PHS had knowledge of the Patents-in-Suit.

37. On March 10, 2017, Larada terminated PHS’s license agreements for breach after PHS failed since January 2017 to pay fees related to the use of the AirAllé device. Although PHS was required to return all of its 25 AirAllé devices within five business days of termination, PHS did not return all the devices until May 2017.

38. Shortly thereafter, Larada discovered that PHS was advertising the use of a very similar device to AirAllé on its website, which PHS calls the FloSonix. Below is a true and correct copy of an image from the PHS website showing the FloSonix device in use.



39. On information and belief, Defendants copied the AirAllé device, including its patented features, to create the FloSonix device. Defendants also use the FloSonix device to infringe the methods claimed in the Patents-in-Suit. Defendants also, through the sale of the FloSonix device and instruction and training of customers, contribute to and induce infringement of the Patents-in-Suit.

40. On information and belief, Defendant FloSonix shares officers and employees with Defendant PHS, and thus has knowledge of the Patents-in-Suit and that the use of the FloSonix device as instructed constitutes infringement of the methods claimed therein.

FIRST CLAIM FOR RELIEF
Infringement of United States Patent No. 7,789,902

41. Larada repeats and realleges the allegations of paragraphs 1-40 above, as if fully set forth herein.

42. Defendants have directly infringed and are still directly infringing the '902 Patent by using the FloSonix device to perform the methods of at least claim 1 of the '902 Patent. On information and belief, Defendant PHS uses the FloSonix device in its clinics for treating individuals with head lice infestations to infringe the '902 Patent. On information and belief, Defendant FloSonix uses the FloSonix device, at least in testing, marketing, and demonstrations to potential customers to infringe the '902 Patent.

43. Defendants have actively induced the infringement of the '902 Patent by selling, leasing or otherwise providing the FloSonix device to customers, and by providing training and/or instruction in its use, with knowledge of the Patents-in-Suit and the specific intent of encouraging, aiding, or causing others to directly infringe the '902 Patent.

44. Defendants have contributed to the infringement of others by selling, leasing or otherwise providing to others the FloSonix device, which is a device especially made or adapted for use in performing the methods of the '902 Patent, the use of which is a material part of the claimed invention, and which is not a

staple article suitable for substantial non-infringing use. Defendants' customers then use the FloSonix device to perform the methods of at least claim 1 of the '902 Patent.

45. For example, with respect to Claim 1 of the '902 Patent, Defendants perform, and instruct their customers to perform, the following steps with the FloSonix device to eliminate an ectoparasite infestation in such a way that results in infringement of the '902 Patent:

- a. Defining a target area on a patient having an ectoparasite infestation, said target area including the patient's hair and scalp.
- b. Using the FloSonix device to heat a volume of air to a temperature to form heated air at a temperature of from, on information and belief, about 54° C to about 65° C.
- c. Using the FloSonix device to apply the heated air to the target area with an airflow of from, on information and belief, about 25 cfm to about 125 cfm, such that the heated air impinges directly on substantially all ectoparasites located within the target area, and wherein the heated air is applied directly to the patient's hair and scalp such that at least a substantial portion of the heated air is forced directly at the patient's scalp from the FloSonix device.

d. Using the FloSonix device to maintain the heated air at the target area for a period of time and at a sufficient airflow to affect an ectoparasite mortality rate of at least 50%.

46. Defendants' acts of infringement were done with knowledge of the Patents-in-Suit, in willful and reckless disregard that Defendants' acts constituted infringement of Larada's patent rights as embodied in the Patents-in-Suit.

47. Defendants' willful infringement of the '902 Patent has caused and will continue to cause Larada significant harm.

SECOND CLAIM FOR RELIEF
Infringement of United States Patent No. 8,162,999

48. Larada repeats and realleges the allegations of paragraphs 1-47 above, as if fully set forth herein.

49. PHS has directly infringed and is still directly infringing the '999 Patent by using the FloSonix device to perform the methods of at least claim 1 of the '999 Patent. On information and belief, Defendant PHS uses the FloSonix device in its clinics for treating individuals with head lice infestations to infringe the '999 Patent. On information and belief, Defendant FloSonix uses the FloSonix device, at least in testing, marketing, and demonstrations to potential customers to infringe the '999 Patent.

50. Defendants have actively induced the infringement of the ‘999 Patent by selling, leasing or otherwise providing FloSonix device to customers, and by providing training and/or instruction in its use, with knowledge of the Patents-in-Suit and the specific intent of encouraging, aiding, or causing others to directly infringe the ‘999 Patent. Defendants’ customers then use the FloSonix device to perform the methods of at least claim 1 of the ‘999 Patent.

51. Defendants have contributed to the infringement of others by selling, leasing or otherwise providing to others the FloSonix device, which is a device especially made or adapted for use in performing the methods of the ‘999 Patent, the use of which is a material part of the claimed invention, and which is not a staple article suitable for substantial non-infringing use. Defendants’ customers then use the FloSonix device to perform the methods of at least claim 1 of the ‘999 Patent.

52. For example, with respect to Claim 1 of the ‘999 Patent, Defendants perform, and then instruct their customers to perform, the following steps with the FloSonix device to eliminate an ectoparasite infestation in such a way that results in infringement of the ‘999 Patent:

- a. Defining a target area on a patient having an ectoparasite infestation, said target area including the patient’s hair and scalp;

- b. Using the FloSonix device to heat a volume of air to a temperature to form heated air at a temperature of from, on information and belief, about 54° C. to about 65° C.
- c. Using the FloSonix device to apply the heated air to the target area with an airflow such that the heated air impinges directly on substantially all ectoparasites located within the target area, and wherein the heated air is applied directly to the patient's hair and scalp such that at least a substantial portion of the heated air is forced directly at and directly contacts the patient's scalp from a device for delivering the heated air.
- d. Using the FloSonix device to maintain the heated air at the target area for a period of time and at a sufficient airflow to affect an ectoparasite mortality rate of at least 50%.

53. Defendants acts of infringement were done with knowledge of the Patents-in-Suit, in willful and reckless disregard that Defendants' acts constituted infringement of Larada's patent rights as embodied in the Patents-in-Suit.

54. Defendants' willful infringement of the '999 Patent has caused and will continue to cause Larada significant harm.

THIRD CLAIM FOR RELIEF
Infringement of United States Patent No. 8,475,510

55. Larada repeats and realleges the allegations of paragraphs 1-54 above, as if fully set forth herein.

56. Defendants have directly infringed and are still directly infringing the ‘510 Patent by using the FloSonix device to perform the methods of at least claim 1 of the ‘510 Patent. On information and belief, Defendant PHS uses the FloSonix device in its clinics for treating individuals with head lice infestations to infringe the ‘510 Patent. On information and belief, Defendant FloSonix uses the FloSonix device, at least in testing, marketing, and demonstrations to potential customers to infringe the ‘510 Patent.

57. Defendants have actively induced the infringement of the ‘510 Patent by selling, leasing or otherwise providing FloSonix device to customers, and by providing training and/or instruction in its use, with knowledge of the Patents-in-Suit and the specific intent of encouraging, aiding, or causing others to directly infringe the ‘510 Patent. Defendants’ customers then use the FloSonix device to perform the methods of at least claim 1 of the ‘510 Patent.

58. Defendants have contributed to the infringement of others by selling, leasing or otherwise providing to others the FloSonix device, which is a device especially made or adapted for use in performing the methods of the ‘510 Patent,

the use of which is a material part of the claimed invention, and which is not a staple article suitable for substantial non-infringing use. Defendants' customers then use the FloSonix device to perform the methods of at least claim 1 of the '510 Patent.

59. For example, with respect to Claim 1 of the '510 Patent, Defendants perform, and instruct their customers to perform, the following steps with the FloSonix device to eliminate an ectoparasite infestation in such a way that results in infringement of the '510 Patent:

- a. Using a disposable applicator tip on the FloSonix device that comprises a plurality of elongated fingers, and wherein at least a subset of the plurality of elongated fingers comprise ports for delivering airflow, and wherein the applicator is configured for delivering heated airflow to a treatment site on the patient.
- b. Connecting the disposable applicator to a heated airflow source of the FloSonix device.
- c. Using the FloSonix device to deliver a heated airflow through the applicator to the treatment site to substantially eliminate the lice and lice eggs from the treatment site.
- d. Moving the applicator to a second treatment site.

- e. Using the FloSonix device to deliver a heated airflow through the applicator to the second treatment site to substantially eliminate the lice and lice eggs from the second treatment site.
- f. Using the FloSonix device to repeat the delivering and moving steps until substantially all lice and lice eggs have been eliminated.
- g. Removing at least a portion of the applicator from the FloSonix device.
- h. Disposing of at least a portion of the applicator.
- i. Connecting a second applicator to the FloSonix device, wherein at least a portion of the second applicator is disposable, and wherein the second applicator is configured for delivering airflow to a treatment site on the patient.

60. PHS's acts of infringement were done with knowledge of the Patents-in-Suit, in willful and reckless disregard that PHS's acts constituted infringement of Larada's patent rights as embodied in the Patents-in-Suit.

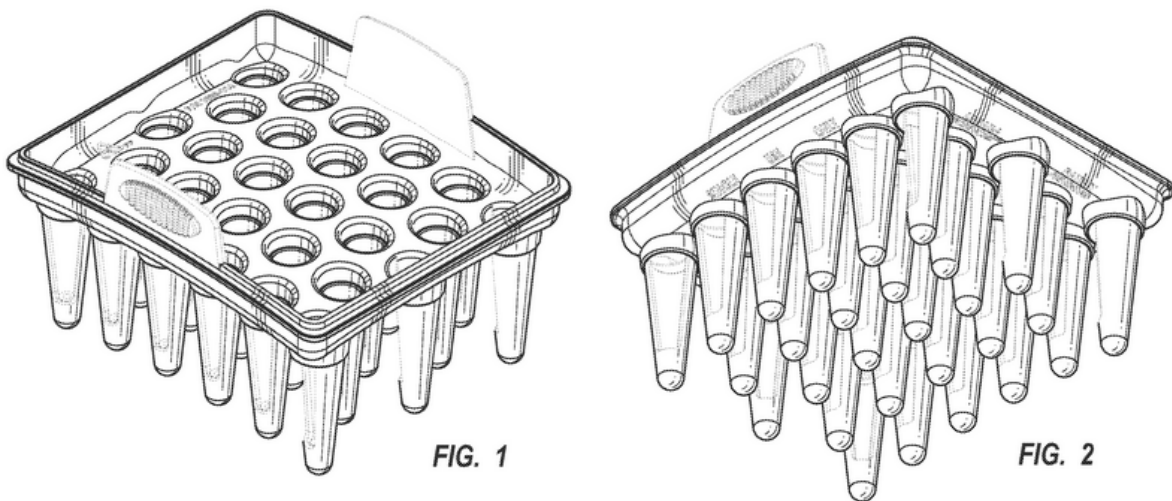
61. PHS's willful infringement of the '510 Patent has caused and will continue to cause Larada significant harm.

FOURTH CLAIM FOR RELIEF
Infringement of United States Patent No. D626,287

62. Larada repeats and realleges the allegations of paragraphs 1-57 above, as if fully set forth herein.

63. The D287 Patent is a design patent that covers the ornamental design of the applicator tip of the AirAllé device.

64. Figures 1 and 2 of the D287 Patent (reproduced below) are representative of the claimed design.



65. As shown below, the D287 Patent also relates to the applicator tip of the AirAllé device that PHS leased from Larada.



Applicator Tip Of The AirAllé Device

66. As shown below, the applicator tip of the FloSonix device is a copy of the ornamental design of the AirAllé.



Applicator Tip Of The FloSonix Device

67. As the following comparison shows, an ordinary observer familiar with the prior art would believe that the applicator tip of the FloSonix device appropriated the design claimed in the D287 Patent, and thus infringes the D287 Patent.



68. Defendants make, use, sell, offer to sell, and import the FloSonix device, including the applicator tip, thus infringing the D287 Patent.

69. Defendants' acts of infringement were done with knowledge of the Patents-in-Suit, in willful and reckless disregard that Defendants' acts constituted infringement of Larada's patent rights as embodied in the Patents-in-Suit.

70. Defendants' willful infringement of the D287 Patent has caused and will continue to cause Larada significant harm.

PRAYER FOR RELIEF

WHEREFORE, Larada respectfully asks this Court to enter a judgment in Larada's favor as follows:

71. Declaring that Defendants have infringed the Patents-in-Suit;
72. Declaring that Defendants' infringement of the Patents-in-Suit was willful, and that Larada is entitled to treble damages pursuant to 35 U.S.C. § 284;
73. Awarding Larada damages adequate to compensate for Defendants' infringing activities, including supplemental damages for any post-verdict infringement up until entry of the final judgment with an accounting as needed, together with prejudgment and post-judgment interest on the damages awarded; all of these damages to be enhanced in an amount up to treble the amount of compensatory damages as justified under 35 U.S.C. § 284;
74. Preliminarily and permanently enjoining Defendants and their officers, agents, directors, employees, parents, subsidiaries, affiliates, divisions, successors, assigns, and all persons in privity or active concert or participation with them, from infringing the Patents-in-Suit;
75. Directing that Defendants destroy or deliver to Larada all documents, materials, and things, including but not limited to products, advertising and

promotional materials, sales and marketing plans, and the like, which infringe the Patents-in-Suit, or otherwise violate Plaintiffs' rights in the Patents-in-Suit;

76. Declaring that this case is exceptional under 35 U.S.C. § 285 and awarding Larada its reasonable costs and expenses of litigation, including attorneys' and experts' fees; and

77. Awarding Larada such other relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

78. Larada demands a trial by jury as to all claims and all issues properly triable thereby.

Dated: June 20, 2018

Respectfully submitted,

/s/ *Phoebe Norton Coddington*

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